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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,782	12/16/2005	Andreas Lendlein	26538-0010	2455

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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06/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/520,782	Applicant(s) LENDLEIN ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 2, 6, 13 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04142005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 04/15/2005.

Election/Restrictions

Applicant's response has been reviewed, and this examiner apologizes for the error in classifying the response as "non-responsive". Further, the election of species is withdrawn.

Applicant's election without traverse of claims 1-16, 18 and 19 in the reply filed on 12/15/2009 is acknowledged.

Claims 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/15/2009.

Claim Objections

Claims 2,6,13 and 16 are objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 2 fails to further limit claim 1 because by definition, and SMP has one or more memory shapes.

Claim 6 fails to further limit the invention because by definition, SMP's have their shape changed though these stimuli.

Claim 13 fails to further limit the invention because in a polymeric drug delivery system, the polymer always controls the release of the drug. This occurs even in non-SMP systems.

Claim 16 fails to further limit the invention in that the hydrolytic characteristics of a biodegradable polymer always define the release of a bioactive from a drug delivery system composed of this polymer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Langer et al (US Patent No. 6,388,043).

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Langer et al teaches a shape memory polymer (SMP) which can hold more than one shape memory, and that these compositions comprise at least one hard segment and at least one soft segment (Abstract; cols. 2-4; col2. 12-15). The reference goes on to teach that the SMP's can be used in the manufacture of vascular stents, medical guide wires and other medical uses (col. 1), The SMP's are characterized as phase segregated linear block co-polymers which have both a hard and soft segment as described above (cols. 1-2) The ability to hold more than one shape memory is disclosed at col.2, lines 51-56. The polymers may be biodegradable (col. 5, lines 6-22). These polymers can be a single or polymer blends. The polymers themselves can be linear, branched, thermoplastic elastomers with side chains or any kind of dendritic structural elements. Stimuli causing shape change can be temperature, ionic change, pH, light, electric field, magnetic field, or ultrasound. Thermoplastic shape memory materials can be shaped (e.g molded) to a desired shape above the T of the hard segment(s) and cooled to a temperature below the shape recovering temperature, where the polymer may undergo mechanical deformation, and strains generated in the polymer. The original shape of the deformed polymers can be recovered by heating them to a temperature higher than their shape recovering temperature. Above this temperature, the strains in the polymer are relieved, allowing the polymer to return to its original shape (see col. 5, lines 23-40; col. 9, lines 25-36; col. 10, lines 59 to col. 11, line 27). Langer et al further teaches the inclusion of bioactive materials, such as inorganic and organic compounds proteins, peptides, polysaccharides such as sugars, lipids, and nucleic acid molecules (cols 15-16). It further suggested that the composition can be

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used in biomedical applications such as, sutures, orthodontic materials, bone screws, nails, plates, Meshes, prosthetics, pumps, catheters, tubes, films, orthopedic braces, splints tape, contact lenses, drug delivery devices, implants, thermal indicators and tissue scaffolds for tissue engineering (col. 16, lines 21-30). Polymers for us in SMP's are listed at cols. 6-9. The instant claims are anticipated by Langer et al

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz